510(k) Summary

K082595

OCT 28 2008

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2000 ext. 13362
Contact Person: Scott Thiel
Date Prepared: September 5, 2008

2) Device name

Proprietary name: ACCU-CHEK® Pocket Compass Diabetes Management Software
Common name: diabetes management software
Classification name: calculator/data processing module for clinical use
Classification Regulations: 880.5725, 862.1345, 862.2100
Product Codes: LZG, LFR, JQP

3) Predicate device

We claim substantial equivalence to the current legally cleared product of the same name.

4) Device Description

An accessory software that enables the person with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results and insulin infusion pump data to support effective diabetes management, including calculating an insulin or carbohydrate dose based on user entered data. The device is not intended to provide any diagnosis based upon patient results.

5) Intended use

The ACCU-CHEK Pocket Compass Diabetes Management Software is a single user system indicated for use as an accessory to compatible Disetronic insulin pumps and a number of commercially available Accu-Chek blood glucose meters to download data from these devices to a personal digital assistant (PDA) where it may be saved, displayed, reviewed, analyzed, and evaluated to support effective diabetes management. The Accu-Chek Pocket Compass Software is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on user entered data. The device is indicated for over-the-counter sale.

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510(k) Summary, Continued

Comparison to Predicate Device

Similarities The Roche Diagnostics ACCU-CHEK Pocket Compass Diabetes Management Software is substantially equivalent to the current legally cleared version of ACCU-CHEK Pocket Compass Diabetes Management Software. The following is a list of some of the claims and features found to be similar to the predicate device.

Feature/Claim	Detail
Meter / pump data download	Yes. Both products allow for the download of historical data stored in the compatible devices
Pump data upload	No. Neither product sends programming or parameter information to the compatible pumps.
Support	Yes; through call center support, labeling and health care professionals.
Data storage	On computer media.
Reports and graphs	Similar graphs and reports can be generated for viewing on a display screen, and hard copy printout.
Manual Data Entry	Same
Delete Data	Same
Track non-blood glucose data	Same
Intended use	Same
Fundamental scientific technology	Same
Security of Bolus Calculator	Same; requires user to communicate to the software with a supported insulin pump before the bolus calculator is active

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2008

Mr. Scott Thiel
Regulatory Affairs Program Manager
Roche Diagnostics
Diabetes Care Division
9115 Hague Road
Indianapolis, Indiana 46250

Re: K082595
Trade/Device Name: ACCU-CHEK® Pocket Compass Diabetes Management
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, LFR, JQP
Dated: October 13, 2008
Received: October 15, 2008

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ACCU-CHEK® Pocket Compass Diabetes Management Software

Indications For Use:

The ACCU-CHEK Pocket Compass Diabetes Management Software is a single user system indicated for use as an accessory to compatible Disetronic insulin pumps and a number of commercially available Accu-Chek blood glucose meters to download data from these devices to a personal digital assistant (PDA) where it may be saved, displayed, reviewed, analyzed, and evaluated to support effective diabetes management. The Accu-Chek Pocket Compass Software is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on user entered data. The device is indicated for over-the-counter sale.

Prescription Use _____ AND/OR Over-The-Counter Use __XX_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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